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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,032	06/20/2003	David J. Hammond	70065.0003USU1	5177

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EXAMINER	
STEELE, AMBER D	

ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
06/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,032	HAMMOND ET AL.	
	Examiner	Art Unit	
	Amber D. Steele	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-27* is/are pending in the application.

4a) Of the above claim(s) *7-10,13,16,17 and 25-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 11-12, 14-15, and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 5, 2007 has been entered.

Status of the Claims

2. The amendment to the claims received on February 5, 2007 amended claims 1 and 12 and canceled claim 18.

Claims 1-17 and 19-27 are currently pending.

Claims 1-6, 11-12, 14-15, and 19-24 are currently under consideration.

Election/Restrictions

3. The elections by applicants in the response received on May 10, 2006 are reiterated: election with traverse of Group I (present claims 1-17 and 19-24) and election without traverse of peptide as the species of ligand, polymethacrylate as the species of support, conditioned cell medium as the species of mixture/composition, protein as the species of entity, and cell proliferation as the species of activity.

The requirement was deemed proper and made FINAL in the Office action mailed on August 3, 2006.

However, upon further consideration, the species requirement for a single, specific species of ligand, a single, specific species of support, and a single, specific species of entity is

withdrawn. The species requirement for a single, specific species of mixture/composition and single, specific species of activity remain and are final.

4. Claims 25-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on May 10, 2006.

5. Claims 7-10, 13, and 16-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on May 10, 2006.

6. Applicants assert in the response received on April 5, 2007 (page 9, second to last paragraph) that present claims 26-27 depend on present claim 1. However, both claim 26 and claim 27 are independent claims that do not depend on claim 1 were withdrawn from consideration as being drawn to nonelected inventions in the non-final Office action mailed on August 3, 2006.

Priority

7. The present application claims benefit of U.S. provisional application 60/395,038 filed on July 11, 2002.

Invention as Claimed

8. A method of screening a mixture for active entities, which method comprises: (i) providing a plurality of different ligands, wherein each ligand is attached to a support t form a

plurality of ligand-support complexes, (ii) contacting the ligand-support complexes with a mixture comprising a plurality of entities under conditions that allow at least one entity to bind to at least one ligand-support complex, thereby forming more than one entity-ligand-support complex, (iii) separating more than one entity-ligand-support complex form the unbound entities, (iv) "complex" assaying the activity of the entity, wherein the entity may be dissociated partially or completely form an entity-ligand-support complex separated in step (iii) and wherein the activity assayed is not solely binding of the entity to the ligand-support complex, (v) detecting the activity, and (vi) selecting at least one entity-ligand-support-complex that bound the entity that exhibited the detected activity whereupon a mixture is screened for active entities and variations thereof.

Specification

9. The disclosure is objected to because of the following informalities: the hexapeptide HPQFLS in the second to last line of paragraph 62 does not have a proper SEQ ID NO: (SEQ ID NO: 1 is suggested).

Appropriate correction is required.

Withdrawn Rejections

10. The rejection of claim 1 under 35 U.S.C. 112, second paragraph regarding the entity is withdrawn in view of the amendment to the claims received on April 5, 2007.

11. The rejection of claims 1-6, 11-12, 14-15, and 20 under 35 U.S.C. 102(b) as being anticipated by Todara U.S. Patent 4,816,561 issued March 28, 1989 is withdrawn in view of the

amendments to the claims received on April 5, 2007 particularly regarding "a plurality of different ligands" and "more than one entity-ligand-support complex".

12. The rejection of claims 1-6, 11-12, 14-15, and 18-24 under 35 U.S.C. 102(b) as being anticipated by Lam et al. U.S. Patent 5,510,240 issued April 23, 1996 is withdrawn in view of the amendments to the claims received on April 5, 2007 particularly regarding "a plurality of different ligands" "attached to a support".

New Rejections

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-6, 11-12, 14-15, and 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "complex" in claim 1, method step (iv) regarding assaying is a relative term which renders the claim indefinite. The term "complex" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, does the term "complex" regarding assaying require specific "complex" skills or "complex" techniques for assaying the activity of the entity, require a M.S. or Ph.D. to perform the assaying due to the level of "complexity", require more than one assay, require assaying binding and an additional activity, etc.?

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-5 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumbach et al. BioPharm. May 1992 pages 24-31 (submitted in IDS).

For present claim 1-5 and 11-12, Baumbach et al. teach methods of screening for binding and activity comprising (i) providing different peptides coupled to agarose beads (i.e. plurality of different ligands attached to support; lignad-support complex), (ii) contacting the peptide-beads with a mixture of streptavidin and streptavidin-alkaline phosphatase (i.e. mixture comprising a plurality of entities; entity-ligand-support; composition comprising chemical compounds; protein complex, protein, organic compound), (iii) washing to remove nonbound (i.e. separating), (iv) assaying for binding and phosphatase activity (i.e. chemical or biochemical activity), (v) detecting phosphatase activity, and (vi) selecting the streptavidin-alkaline phosphatase (please refer to entire reference particularly "Materials and Methods" section, Figure 2).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 1-6, 11-12, 14-15, and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. Analytical Biochemistry 294: 55-62, July 1, 2001 and Lam et al. U.S. Patent 5,510,240 issued April 23, 1996.

For present claims 1-2, 4-6, 11-12, Huang et al. teach methods for simultaneous detection of multiple cytokines from conditioned media and patient's sera by an antibody-based protein array system comprising (i) adding capture antibodies (i.e. ligands; proteins) onto a Hybond ECL membrane (i.e. support; nitrocellulose) wherein different antibodies (i.e. plurality of different ligands) can be utilized and the membrane can be cut into strips thus creating a plurality of ligand-support complexes, (ii) contacting the ligand-support complexes with conditioned medium or patient sera (i.e. mixture comprising a plurality of entities; protein, antibody, cell, organic compound, protein complex, bacteria, virus, etc. entities) thus creating an entity-ligand-support complex or more than one entity-ligand-support complexes wherein more than one membrane strip is utilized, (iii) washing to remove non-bound entities (i.e. separating), (iv) assaying for binding (i.e. physical activity), (v) detecting binding, and selecting the "binders" (please refer to the entire references particularly the "Methods" section).

However, Huang et al. does not specifically teach detecting an activity other than binding.

For present claim 1, Lam et al. teach methods of screening peptide libraries utilizing a library of bio-oligomers (i.e. entities) attached to solid phase supports, introducing an acceptor molecules or substrate molecule including antibodies which can be bound onto solid phase support (i.e. ligand-support; column 18, lines 30-36) that recognizes and binds the bio-oligomer (i.e. entity), washing nonbound molecules from the mixture, assaying for binding and

biological/physical/chemical/biochemical reactions including enzyme activity, toxicity, growth promotion, etc., detecting binding and the biological/physical/chemical/biochemical reactions, and isolating a support/bio-oligomer/molecule with the desired property including binding, stimulation, inhibition, toxicity, etc. (e.g. activity) (please refer to abstract; sections 1, 3, 5.1, 5.4, 5.5 including 5.5.1-5.5.3; Example sections 6-14; Figures 1-2 and 4-8D).

For present claims 2-3, Lam et al. teach that the ligands can be peptides or nucleic acids (please refer to sections 5.1, 5.2, 5.3).

For present claim 4, Lam et al. teach that the supports can be silica, resin, plastic films, glass beads, alumina gels, polystyrene, polydimethylacrylamide (e.g. polymethacrylate; please refer to section 5.4).

For present claims 5-6, Lam et al. teach that the cells and conditioned culture medium can be utilized in the screening methods (please refer to sections 5.5.2.1).

For present claim 11, Lam et al. teach that the molecule (e.g. entity) can be protein, antibody, enzyme, cell, receptor, virus, carbohydrate, drugs, lipids (please refer to sections 5.5, 5.5.1).

For present claims 12 and 14-15, Lam et al. teach determining activities including binding, stimulation, inhibition, toxicity, enzyme activity, killing, growth promotion, physiological change (please refer to sections 5.5 including 5.5.1, 5.5.2).

For present claim 19, Lam et al. teach that the beads can be partitioned and separated into smaller pools (e.g. subpools; please refer to sections 5.5.1, 5.5.2).

For present claims 20 and 23, Lam et al. teach identifying peptide sequences including sequencing (please refer to section 5.5.2; Tables 1-5; Examples 10-13).

For present claims 21 and 22, Lam et al. teach that the screening assay can repeated several times and that cleavable linkers can be utilized to recover the peptides bound to the supports (sections 5.1, 5.5.1, 5.5.2, 5.4).

For present claim 24, Lam et al. teach that cleavage and/or release of the components of the molecule-peptide-support is possible (please refer to 5.1, 5.5.1, 5.5.2, 5.4).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the methods for simultaneous detection of multiple cytokines from conditioned media and patient's sera by an antibody-based protein array system taught by Huang et al. with the methods taught by Lam et al. combining methods for screening for binding and other "activities".

One having ordinary skill in the art would have been motivated to do this because it would be a natural progression in the experimental process to find an entity and then determine what the activity of the entity is (i.e. screen for a molecule via binding then screen for other activities).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the methods for simultaneous detection of multiple cytokines from conditioned media and patient's sera by an antibody-based protein array system taught by Huang et al. with the methods taught by Lam et al. combining methods for screening for binding and other "activities" because Huang et al. teach that the cytokines they screened for binding play important roles in innate immunity, apoptosis, angiogenesis, cell growth, and cell differentiation (please refer to page 61, left column, last paragraph).

Therefore, the modification of the methods for simultaneous detection of multiple cytokines from conditioned media and patient's sera by an antibody-based protein array system taught by Huang et al. with the methods taught by Lam et al. combining methods for screening for binding and other "activities" render the instant claims *prima facie* obvious.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ADS
June 14, 2007

MARK L. SHIBUYA
PRIMARY EXAMINER